IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF NEW YORK

MARCIA SABOL, Plaintiff, vs. BAYER HEALTHCARE PHARMACEUTICALS INC.; BAYER CORPORATION; BAYER HEALTHCARE LLC; BRACCO DIAGNOSTICS, INC.; GE HEALTHCARE INC.; GENERAL ELECTRIC COMPANY; and McKESSON CORPORATION, Defendants.	Civil Action No. 1:18-cv-11169 (VM)

PLAINTIFF'S FIRST AMENDED COMPLAINT FOR DAMAGES

COMES NOW Plaintiff, MARCIA SABOL, by and through undersigned counsel, and alleges as follows:

1. Gadolinium is a highly toxic heavy metal and rare earth element. It does not occur naturally in the human body. The only known route for gadolinium to enter the human body is by injection of a gadolinium-based contrast agent.

2. Plaintiff Marcia Sabol was injected with the linear gadolinium-based contrast agents ("GBCA") Magnevist, MultiHance, and Omniscan prior to receiving several MRIs. Contrary to the defendants' promotion of GBCAs as benign contrast agents that harmlessly exit the body shortly after administration in patients with normal kidney function, Ms. Sabol continues to have retained gadolinium in her body, years after being administered the GBCAs. Among others, Ms. Sabol received the following linear GBCA administrations on or around the following dates:

a) May 18, 2007 – Magnevist – New York

b) July 24, 2008 – Magnevist – New York

c) August 23, 2008 – Magnevist – New York

d) August 29, 2008 – Magnevist – New York

e) October 20, 2008 – Magnevist – New York

f) November 21, 2008 – Omniscan – Florida

g) November 25, 2008 – Omniscan – Florida

h) November 26, 2008 – Omniscan – Florida

i) January 28, 2009 – Magnevist – New York

j) April 13, 2009 – Magnevist – New York

k) July 20, 2009 – Magnevist – New York

l) October 19, 2009 – Magnevist – Connecticut

m) February 1, 2010 – Magnevist – Connecticut

n) February 8, 2010 – Magnevist -- Connecticut

o) March 4, 2010 – Magnevist – New York

p) March 20, 2010 – Magnevist – New York

q) June 11, 2010 – Magnevist – New York

r) June 22, 2010 – Magnevist – New York

s) December 4, 2010 – Magnevist – New York

t) April 19, 2011 – Magnevist – Connecticut

u) September 24, 2012 – Magnevist - Connecticut

v) October 7, 2014 – MultiHance – Florida

w) July 10, 2015 – Magnevist – New York

3. On or around April 8, 2016, Marcia Sabol underwent a urine test for heavy metals, and the testing reported that she had high levels of gadolinium retained in her body. It was then that Ms. Sabol discovered her physical condition and the latent toxic levels of gadolinium in her body

4. Plaintiff's primary injury alleged herein is caused by gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin). The gadolinium, a toxic heavy metal, caused fibrosis in Plaintiff's organs, bone, and skin, and crossed the blood-brain barrier

and deposited in the neuronal nuclei of her brain. As a result, Plaintiff suffers from the following symptoms, among others: cognitive impairment, pain, impaired mobility, bone and joint pain, muscle pain, numbing sensation in extremities, burning sensation, depression, and anxiety. These adverse effects were reasonably foreseeable based on what Defendants knew or should have known at the time of Ms. Sabol's administrations of Magnevist, Multihance, and Omniscan.

5. Marcia Sabol is a 53-year-old disabled Registered Nurse. Prior to onset of her gadolinium-related symptoms, she graduated from the Cochran School of Nursing in New York with a 4.0 GPA. She was athletic, healthy, intelligent, and had an excellent memory.

6. Ms. Sabol notes that her activities of daily living have been severely impacted by her gadolinium retention. For example, her bone and joint pain have severely limited Ms. Sabol's mobility. She has difficulty walking without a walker. Furthermore, Ms. Sabol's cognition as a result of gadolinium retention is impaired, making it difficult for her to read and perform other ordinary tasks.

7. Toxic gadolinium deposits were identified and diagnosed in Ms. Sabol's body by treating physicians.

8. Ms. Sabol was never warned about the risks of gadolinium retention because she had normal renal function and the GBCA manufacturers chose to only provide warnings to patients with reduced renal function.

9. This is an action for damages suffered by Ms. Sabol as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distribution, labeling, and/or sale of the pharmaceutical drugs Magnevist, MultiHance, and Omniscan, linear gadolinium-based contrast agents used in MRIs.

10. Magnevist, MultiHance, and Omniscan are defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lack proper warnings and directions as to the dangers associated with their use.

11. The gadolinium from Magnevist, MultiHance, and Omniscan did not leave Ms. Sabol's body as Defendants promised it would, and instead Ms. Sabol retained it permanently in multiple organs, including her brain, heart, liver, kidney, bones, and skin. The gadolinium caused fibrosis in her organs, bone, and skin, and crossed the blood-brain barrier and deposited in the neuronal nuclei of her brain.

JURISDICTION AND VENUE

12. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because Defendants are all incorporated and have their principal places of business outside of the state in which the Plaintiff resides.

13. There is complete diversity of citizenship between Plaintiff and Defendants. Plaintiff is currently a resident and citizen of the state of Florida, however, Plaintiff was a resident of New York for the majority of the GBCA administrations at issue in this Complaint.

14. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

15. This Court has personal jurisdiction over Defendants, each of which is licensed to conduct and is systematically and continuously conducting business in the State of New York, including, but not limited to, the marketing, researching, testing, advertising, selling, and distributing of drugs, including Magnevist, MultiHance, and Omniscan, to the residents of this state, including Plaintiff.

16. The Bayer Defendants, at all relevant times, have and had significant contacts with the State of New York. The Bayer Defendants are all registered to do business in the State of New York with the New York Secretary of State. The Bayer Defendants operated at facility in Tarrytown, New York. The Bayer Defendants conducted clinical trials and other research regarding Magnevist in the State of New York. The Bayer Defendants sold the Magnevist that was administered to Plaintiff in the State of New York. Plaintiff received injections of Defendant's Magnevist in the State of New York.

17. Defendant General Electric Company is a New York company with its principle

place of business in Massachusetts. Defendant General Electric Company engaged in the manufacturing, testing, licensing, design, marketing, selling, distributing, and advertising of Omniscan in the State of New York.

18. Defendant McKesson Corporation at all relevant times, has and had significant contacts with the State of New York. Defendant McKesson Corporation is registered to do business in the State of New York with the New York Secretary of State. Defendant McKesson Corporation distributed and sold the Magnevist that was administered to Plaintiff in the State of New York and the MultiHance and Omniscan that were distributed to Plaintiff in other states. Plaintiff received the injections of Magnevist in the State of New York.

19. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the Defendants conduct business in New York and are subject to personal jurisdiction in this District. Defendants sell, advertise, market and/or distribute Magnevist, MultiHance, and Omniscan within the Southern District of New York, and do substantial business in this state and within this District.

20. The events that give rise to this lawsuit occurred primarily in New York. Defendants' actions that give rise to this lawsuit occurred primarily in New York.

21. Defendants developed, manufactured, promoted, marketed, tested, researched, distributed, warranted, and sold Magnevist, MultiHance, and Omniscan in interstate commerce.

PARTIES

22. At many times relevant to this complaint, Plaintiff Marcia Sabol was a resident of the Southern District of New York. Plaintiff currently resides in Florida.

23. Ms. Sabol has had approximately fourteen MRIs in the State of New York. Before each, she was injected with linear gadolinium-based contrast agents in the State of New York. Plaintiff has had approximately five MRIs in the State of Florida. Before each, she was injected with linear gadolinium-based contrast agents. Plaintiff had approximately five MRIs in Connecticut, but she was a resident of New York at the time. Before each, she was injected with linear gadolinium-based contrast agents.

24. Ms. Sabol was never warned about the risks of gadolinium retention because she did not have chronic/severe kidney disease or acute kidney injury, and the Defendant GBCA manufacturers chose to only provide warnings to patients with these types of reduced renal function.

25. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, and Bayer Healthcare LLC (collectively referred to as the "Bayer Defendants') manufacture, market, and sell Magnevist, a gadolinium-based contrast agent that was injected into Plaintiff's body.

26. Defendant Bayer Healthcare Pharmaceuticals Inc. is a for-profit Delaware corporation with its principal place of business in New Jersey, where its headquarters are located and from where its officers direct, control, and coordinate the company's activities. Bayer Healthcare Pharmaceuticals Inc. is thus a citizen of both the State of Delaware and the State of New Jersey. Defendant Bayer Healthcare Pharmaceuticals Inc. is the United States pharmaceuticals unit of Bayer Healthcare LLC. Bayer Healthcare Pharmaceuticals Inc. is engaged in the business of testing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Defendant Bayer Healthcare Pharmaceuticals Inc. actively marketed and caused to be distributed Magnevist to hospitals and radiological facilities in the State of New York throughout the entire time period in question.

27. Bayer Corporation is the sole member of Bayer Healthcare LLC. Bayer Corporation is incorporated under the laws of the State of Indiana with its principal place of business in New Jersey. Bayer Corporation is thus a citizen of both the State of Indiana and New Jersey. Defendant Bayer Corporation is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities. This court has

personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Defendant Bayer Corporation actively marketed and caused to be distributed Magnevist to hospitals and radiological facilities in the State of New York throughout the entire time period in question.

28. Bayer HealthCare LLC is engaged in the business of testing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over Defendant Bayer HealthCare LLC under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Defendant Bayer Healthcare LLC actively marketed and caused to be distributed Magnevist to hospitals and radiological facilities in the State of New York throughout the entire time period in question.

29. Defendant Bayer HealthCare LLC is a for-profit limited liability company organized under the laws of Delaware. Bayer HealthCare LLC contends that its principal place of business is in New Jersey. Bayer HealthCare LLC is registered to do business in New York and one of its member's principal place of business is in New York (NippoNex Inc.). The officers of Bayer HealthCare LLC reside in Pennsylvania, New Jersey, Kansas, and California.

30. Bayer HealthCare LLC is a nongovernmental entity. It is a Delaware limited liability company whose members are NippoNex Inc., Bayer Medical Care Inc., Bayer West Coast Corporation, Bayer Essure, Inc., Bayer Consumer Care Holdings LLC, Dr. Scholl's LLC, Coppertone LLC, MiraLAX LLC, and Bayer HealthCare US Funding LLC, and as such Bayer HealthCare LLC is owned by those entities. Therefore, Bayer HealthCare LLC certifies that it has nine (9) members/owners.

a) The first member/owner of Bayer HealthCare LLC is NippoNex Inc. NippoNex Inc. is a Delaware corporation. NippoNex Inc.'s principal place

of business is in New York.

b) The second member/owner of Bayer HealthCare LLC is Bayer Medical Care Inc. Bayer Medical Care Inc. is a Delaware corporation. Bayer Medical Care Inc.'s principal place of business is in Pennsylvania.

c) The third member/owner of Bayer HealthCare LLC is Bayer West Coast Corporation. Bayer West Coast Corporation is a Delaware corporation. Bayer West Coast Corporation's principal place of business is in California.

d) The fourth member/owner of Bayer HealthCare LLC is Bayer Essure, Inc. Bayer Essure, Inc. is a Delaware corporation. Bayer Essure, Inc.'s principal place of business is in California.

e) The fifth member/owner of Bayer HealthCare LLC is Bayer Consumer Care Holdings LLC. Bayer Consumer Care Holdings LLC's principal place of business is in New Jersey. Bayer Consumer Care Holdings LLC is a Delaware limited liability company whose sole common member is Bayer East Coast LLC, and whose sole preferred member is Bayer HealthCare US Funding LLC. Bayer East Coast LLC is a Delaware limited liability company, whose sole member is Bayer US Holding LP, and as such, is wholly-owned by Bayer US Holding LP. Bayer US Holding LP is a Delaware limited partnership. Bayer HealthCare US Funding LLC is a Delaware limited liability company whose members are Bayer AG, Bayer Pharmaceuticals AG, and Bayer World Investments B.V. Bayer AG is a German corporation. Bayer Pharmaceuticals AG is a German corporation. Bayer World Investments B.V. is a private company with limited liability incorporated under the laws of the Netherlands and is wholly-owned by Bayer AG.

f) The sixth member/owner of Bayer HealthCare LLC is Dr. Scholl's LLC. Dr. Scholl's LLC's principal place of business is in California. Dr. Scholl's

LLC is a Delaware limited liability company. The sole member/owner of Dr. Scholl's LLC is Bayer HealthCare US Funding LLC. Bayer HealthCare US Funding LLC is a Delaware limited liability company whose members are Bayer AG, Bayer Pharmaceuticals AG, and Bayer World Investments B.V. Bayer AG is a German corporation. Bayer Pharmaceuticals AG is a German corporation. Bayer World Investments B.V. is a private company with limited liability incorporated under the laws of the Netherlands and is wholly-owned by Bayer AG.

g) The seventh member/owner of Bayer HealthCare LLC is Coppertone LLC. Coppertone LLC's principal place of business is in California. Coppertone LLC is a Delaware limited liability company. The sole member/owner of Coppertone LLC is Bayer HealthCare US Funding LLC. Bayer HealthCare US Funding LLC is a Delaware limited liability company whose members are Bayer AG, Bayer Pharmaceuticals AG, and Bayer World Investments B.V. Bayer AG is a German corporation. Bayer Pharmaceuticals AG is a German corporation. Bayer World Investments B.V. is a private company with limited liability incorporated under the laws of the Netherlands and is wholly-owned by Bayer AG.

h) The eighth member/owner of Bayer HealthCare LLC is MiraLAX LLC. MiraLAX LLC is a Delaware limited liability company. MiraLAX LLC's principal place of business is in California. The sole member/owner of MiraLAX LLC is Bayer HealthCare US Funding LLC. Bayer HealthCare US Funding LLC is a Delaware limited liability company whose members are Bayer AG, Bayer Pharmaceuticals AG, and Bayer World Investments B.V. Bayer AG is a German corporation. Bayer Pharmaceuticals AG is a German corporation. Bayer World Investments B.V. is a private company with limited liability incorporated under the laws of the Netherlands and is

wholly-owned by Bayer AG.

i) The Ninth member/owner of Bayer HealthCare LLC is Bayer HealthCare US Funding LLC. Bayer HealthCare US Funding LLC's principal place of business is in Pennsylvania. Bayer HealthCare US Funding LLC is a Delaware limited liability company whose members are Bayer AG, Bayer Pharmaceuticals AG, and Bayer World Investments B.V. Bayer AG is a German corporation. Bayer Pharmaceuticals AG is a German corporation. Bayer World Investments B.V. is a private company with limited liability incorporated under the laws of the Netherlands and is wholly-owned by Bayer AG.

31. Accordingly, Bayer HealthCare LLC is a citizen of Delaware, New Jersey, Indiana, Pennsylvania and California for purposes of determining diversity under 28 U.S.C. § 1332.

32. Defendant Bracco Diagnostics Inc. manufactures, tests, markets, advertises, and sells the linear GBCA named MultiHance.

33. Defendant Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business in New Jersey. Bracco Diagnostics, Inc. is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing MultiHance into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Defendant Bracco Diagnostics Inc. actively marketed and caused to be distributed MultiHance to hospitals and radiological facilities in the State of New York throughout the entire time period in question.

34. Defendants GE Healthcare Inc. and General Electric Company manufacture, market, and sell Omniscan, a gadolinium-based contrast agent ("GBCA") that was injected into Plaintiff's body.

35. Defendant GE Healthcare Inc. is incorporated under the laws of the State of Delaware with its principal place of business in Boston, Massachusetts, where its headquarters are located and from where its officers direct, control, and coordinate the company's activities. GE Healthcare Inc. is thus a citizen of both the State of Delaware and the Commonwealth of Massachusetts. GE Healthcare Inc. is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Omniscan into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Defendant GE Healthcare Inc. actively marketed and caused to be distributed Omniscan to hospitals and radiological facilities in the State of New York throughout the entire time period in question.

36. Defendant General Electric Company is incorporated under the laws of the State of New York with its principal place of business in Boston, Massachusetts, where its headquarters are located and from where its officers direct, control, and coordinate the company's activities. General Electric Company is thus a citizen of both the State of New York and the Commonwealth of Massachusetts. General Electric Company is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Omniscan into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities. Defendant General Electric Company actively marketed and caused to be distributed Omniscan to hospitals and radiological facilities in the State of New York throughout the entire time period in question.

37. Defendant McKesson Corporation ("McKesson") distributes Magnevist, MultiHance, Omniscan, and other gadolinium-based contrast agents in New York. Plaintiff alleges that McKesson distributed the Magnevist, MultiHance, and Omniscan that was injected

into Plaintiff. Defendant McKesson Corporation actively marketed and caused to be distributed Magnevist, Multihance, and Omniscan to hospitals and radiological facilities in the State of New York throughout the entire time period in question.

38. Defendant McKesson Corporation is a Delaware corporation with its principal place of business in Texas. McKesson Corporation is duly authorized to conduct business in the State of New York and does significant business in the State of New York. McKesson is engaged in the business of storing, distributing, selling, marketing, and/or introducing Magnevist, MultiHance, and Omniscan into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

39. As used herein, "Defendants" includes Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, and Bayer Healthcare LLC, Bracco Diagnostics, Inc., GE Healthcare Inc., General Electric Company, and McKesson Corporation.

40. Defendants are authorized to do business in the Southern District of New York and derive substantial income from doing business in this state.

41. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities with the Southern District of New York, thus invoking the benefits and protections of its laws.

42. Upon information and belief, Defendants did act together to design, manufacture, advertise, market, promote, sell, and/or distribute Magnevist, MultiHance, and Omniscan with full knowledge of the dangerous and defective nature of these drugs.

FACTS COMMON TO ALL CAUSES OF ACTION

43. Gadolinium is a rare earth metal and chemical element, abbreviated on the periodic table as "Gd."

44. Gadolinium-Based Contrast Agents (GBCAs) are chemical compounds that are

introduced into the body prior to an MRI procedure in order to enhance the imaging. There are two classes of GBCAs: linear and macrocyclic. Plaintiff alleges that her injuries were caused by the linear GBCAs that she received because, as explained below, the linear GBCAs are less chemically stable than macrocyclic GBCAs.

45. Gadolinium is toxic. It does not occur naturally in the body, and it is well accepted in the medical and scientific community that "free" gadolinium is toxic in biological systems. Gadolinium has no role or function in the human body and is not required for human health, but it is a well-known toxicant and is known to be injurious to humans.

46. Because gadolinium cannot be safely introduced into the body by itself, GBCAs instead are comprised of "chelated" gadolinium –*i.e.*, Gd^{3+} that is complexed (or "bound" by a ligand). Thus, the gadolinium in a GBCA was originally intended to remain chelated as it passes through and eventually is eliminated from the body, mainly by the kidneys, after the MRI.

47. Because of the structure of GBCAs, there is a risk of "de-chelation," a process whereby gadolinium can become unbound or freed from its chelate. De-chelation is due in part to the fact that other substances in the body will "compete" with gadolinium for its chelate, including zinc, copper, and iron. In fact, the bond in a GBCA can become very weak and separate very easily in low pH conditions, such as those found in many compartments of the human body, including extracellular fluid spaces.

48. Once de-chelated, the freed, highly-reactive cation Gd^{3+} will immediately – within seconds – bind to another substance in the body, and there are a variety of substances in the human body that are available to, and known to bind with, de-chelated Gd^{3+}, including proteins, phosphates and other compounds.

49. The estimated US market for GBCAs is at least $300 million per year. The national estimate of GBCA sales from US manufacturers to non-retail channels[1] of distribution ranged from 7.5 million - 8.8 million packages sold annually during an FDA review period.

[1] Outlets within the non-retail market include clinics, non-federal hospitals, federal facilities, HMOs, long-term care facilities, home health care, and other miscellaneous settings

GBCAs were widely sold from 2006 through 2016 in the United States. In 2006, an estimated 8.6 million packages of GBCAs were sold, primarily to hospitals and clinics. Linear GBCAs accounted for 95% (8.2 million packages) of total sales. However, by 2016, sales of macrocyclic GBCAs accounted for 51% (4.5 million packages), and linear GBCAs accounted for 49% (4.3 million packages) of the estimated 8.8 million packages sold. [2]

50. Plaintiff Marcia Sabol underwent MRIs during which she was injected with linear GBCAs. Plaintiff had normal kidney function at the time she was injected with these GBCAs. The gadolinium that Ms. Sabol was injected with was retained in her body and resulted in fibrosis in her organs, skin, and bones, retained gadolinium in the neuronal nuclei of her brain, and related injuries.

51. The type of gadolinium retention sustained by Plaintiff occurs in patients without chronic/severe kidney disease or acute kidney injury who develop persistent symptoms that arise hours to months after the administration of a linear gadolinium-based contrast agent. Plaintiff had no preexisting disease or subsequently-developed disease of an alternate known process to account for the symptoms. This is a progressive condition for which there is no known cure.

52. During the years that Defendants manufactured, marketed, distributed, sold, and administered linear gadolinium-based contrast agents, there have been numerous case reports, studies, assessments, papers, peer reviewed literature, and other clinical data that have described and/or demonstrated gadolinium retention in connection with the use of linear gadolinium-based contrast agents.

53. Notwithstanding many studies documenting retention of toxic gadolinium in the bones, skin, organs and brains of people with normal kidney function, as well as thousands of adverse event reports by people with normal kidney function, none of the Defendants made any effort whatsoever to obtain a label change between 2007, when a black box warning was added, and September 2017, when the FDA MIDAC meeting was held to revisit linear GBCA

[2] Exhibit A - FDA Medical Imaging Drugs Advisory Committee Meeting; Gadolinium Retention after Gadolinium Based contrast Magnetic Resonance Imaging in Patients with Normal Renal Function; Briefing Document; September 8, 2017; Pg. 101.

labeling. The Defendants could easily have initiated such a change as evidenced by the joint warning issued in May, 2018, which was the product of evidence that had been known to the Defendants for years.

54. Defendants discovered newly acquired information after the FDA's initial approval of their drugs' labels many years ago. This new information was regarding the risks and dangers of retention and physical injuries associated therefrom of linear gadolinium-based contrast agents. Defendants had newly acquired information evidencing:

a) Gadolinium is retained for months or years in several organs

b) The highest concentrations have been identified in the bone, followed by other organs (e.g. brain, skin, kidney, liver, and spleen)

c) The duration of retention varies by tissue and is longest in bone

d) Linear GBCAs cause more retention that macrocyclic GBCAs

e) At equivalent doses, gadolinium retention varies among the linear agents with Omniscan and Optimark causing greater retention than other linear agents such as Eovist, Magnevist, and Multihance

f) Retention is lowest and similar among the macrocylic GBCAs

g) Pathologic and/or clinical consequences such as skin changes have been reported in patients with normal renal function

h) Adverse events involving multiple organ systems have been reported in patients with normal renal function

i) Certain patients may be at higher risk for gadolinium retention and risks associated therefrom, including:

1. Patients requiring multiple lifetime doses
2. Pregnant patients
3. Pediatric patients
4. Patients with inflammatory conditions

j) Patients should minimize repetitive GBCA imaging studies, particularly

closely spaced studies when possible

k) Gadolinium deposits within the nerve cells of recipients[3]

l) Linear GBCAs lead to greater systemic toxicity and significantly greater skin fibrosis than macrocyclic GBCAs[4]

m) Bone marrow possess a 'memory' of prior gadolinium contrast exposure[5]

n) Administration of a linear GBCA into the brains of rats caused a number of behavioral and neurologic effects including muscle jerking, loss of control of bodily movements, weakness, tremors, and pathologic brain abnormalities[6]

o) Intravenous linear GBCA increased seizures in dogs when the permeability of the blood brain barrier was altered[7]

p) Abnormal brain signals in multiple regions have been documented in patients with histories of prior GBCA exposure and normal renal function[8]

q) Perinatal exposure to GBCAs in mice caused anxiety-like behavior, increased tactile sensitivity, impaired motor coordination, disrupted memory, and decreased muscular strength in offspring[9]

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[3] McDonald, R.J., et al., Intracranial Gadolinium Deposition after Contrast enhanced MR Imaging. Radiology, 2015. 275(3): p. 772-82.
[4] Runge, V.M., Dechelation (Transmetalation): Consequences and Safety Concerns With the Linear Gadolinium-Based Contrast Agents, In View of Recent Health Care Rulings by the EMA (Europe), FDA (United States), and PMDA (Japan). Invest Radiol, 2018. 53(10): p. 571-578.
[5] Drel, V.R., et al., Centrality of bone marrow in the severity of gadolinium-based contrast-induced systemic fibrosis. FASEB J, 2016. 30(9): p. 3026-38
[6] Ray, D.E., et al., Neurotoxic effects of gadopentetate dimeglumine: behavioral disturbance and morphology after intracerebroventricular injection in rats. AJNR Am J Neuroradiol, 1996. 17(2): p. 365-73.
[7] Roman-Goldstein, S.M., et al., Effects of gadopentetate dimeglumine administration after osmotic blood-brain barrier disruption: toxicity and MR imaging findings. AJNR Am J Neuroradiol, 1991. 12(5): p. 885-90.
[8] Bolles, G.M., et al., Development of High Signal Intensity within the Globus Pallidus and Dentate Nucleus following Multiple Administrations of Gadobenate Dimeglumine. AJNR Am J Neuroradiol, 2018.
[9] Ersoy, H. and F.J. Rybicki, Biochemical safety profiles of gadolinium-based extracellular contrast agents and nephrogenic systemic fibrosis. J Magn Reason Imaging, 2007. 26(5): p.

r) Repeated injections of a linear GBCA into the epidural space of a woman led to seizures and the requirement for mechanical ventilation in a critical care unit[10]

s) Accidental intrathecal injection of a linear GBCA in a patient led to a persistent vegetative state[11]

t) Repeated GBCA administrations in a 57-year old woman led to "gadolinium encephalopathy" characterized by drowsiness, fluctuations levels of consciousness, and mild left-sided paralysis[12]

u) Gadolinium-associated skin plaques have been reported in patients without kidney disease[13]

v) A 58-year old woman with normal renal function was exposed to a single dose of a linear GBCA and a physical exam 7 years later was notable for skin discoloration, skin tightness, red and rubbery skin texture, and a biopsy three years after exposure demonstration fibrosis, alopecia, and high levels of gadolinium in her hair and urine[14]

w) The specific markers for GBCA-induced fibrosis have been found in a patient with normal renal function who had received many linear GBCA administrations including a skin biopsy positive for gadolinium and joint contractures[15]

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[10] Kapoor, R., et al., Gadolinium encephalopathy after intrathecal gadolinium injection. Pain Physician, 2010. 13(5): p. E321-6.

[11] Exhibit A to Complaint. FDA. Medical Imaging Drugs Advisory Committee Meeting. Gadolinium retention after gadolinium based contrast magnetic resonance imaging in patients with normal renal function. Briefing document. 2017

[12] Maramattom, B.V., et al., Gadolinium encephalopathy in a patient with renal failure. Neurology, 2005. 64(7): p. 1276-8.

[13] Gathings, R.M., et al., Gadolinium-associated plaques: a new, distinctive clinical entity. JAMA Dermatol, 2015. 151(3): p. 316-9.

[14] Semelka, R.C., et al., Presumed Gadolinium Toxicity in Subjects With Normal Renal Function: A Report of 4 Cases. Invest Radiol, 2016. 51(10): p. 661-5.

[15] Roberts, D.R., et al., High Levels of Gadolinium Deposition in the Skin of a Patient With Normal Renal Function. Invest Radiol, 2016. 51(5): p. 280-9.

x) High amounts of gadolinium have been found in the hearts of patients with GBCA-induced systemic fibrosis[16]

y) Diffuse myocardial fibrosis, subendocardial fibrous plaques, scarring of the lungs and heart are risks of GBCA-induced systemic fibrosis[17]

z) GBCAs cause respiratory symptoms such as difficulty breathing

aa) GBCAs are toxic to kidneys [18]

bb) Gadolinium has been found in the kidneys of linear GBCA-treated rats in addition to pathologic abnormalities[19]

cc) Gadolinium and markers of fibrosis have been found in the liver of linear GBCA-treated rats. *Id.*

55. Bayer's own scientists have written in published literature that free gadolinium "can have adverse biologic effects." Lohrke, J et al., Histology and Gadolinium Distribution in the Rodent Brain After the Administration of Cumulative High Doses of Linear and Macrocyclic Gadolinium-Based Contrast Agent. Invest. Radiol, 2017. 52(6). This constitutes newly acquired information that should have been submitted to FDA.

56. In 2016, Drs. Derrick Todd and Jonathan Kay published in *The Annual Review of Medicine* urging the medical community to stop using the term "NSF" and instead use the term "gadolinium-induced fibrosis." They wrote:

> "Gd [gadolinium], not kidney tissue, is the source of disease… We encourage the medical community to embrace the term GIF [gadolinium-induced fibrosis] as a more accurate description of this chronic fibrosing disorder that is triggered by Gd [gadolinium]. The term GIF also permits greater scientific plasticity when considering the larger universe of fibrosing disorders and what has yet to be

[16] Swaminathan, S., et al., Cardiac and vascular metal deposition with high mortality in nephrogenic systemic fibrosis. Kidney Int, 2008. 73(12): p. 1413-8.
[17] Jimenez, S.A., et al., Dialysis-associated systemic fibrosis (nephrogenic fibrosing dermopathy): study of inflammatory cells and transforming growth factor beta1 expression in affected skin. Arthritis Rheum, 2004. 50(8): p. 2660-6.
[18] Boyden, T.F. and H.S. Gurm, Does gadolinium-based angiography protect against contrast-induced nephropathy?: a systematic review of the literature. Catheter Cardiovasc Interv, 2008. 71(5): p. 687-93.
[19] Do, C., et al., Type of MRI contrast, tissue gadolinium, and fibrosis. Am J Physiol Renal Physiol, 2014. 307(7): p. F844-55.

> learned about Gd [gadolinium] toxicity….Thus, the term GIF makes known the causative role of GBCAs in this disease, which should help eliminate the inadvertent administration of high-risk agents to at-risk patients, lest future generations forget past experience with yet another toxin-induced fibrotic disorder." Todd, D, Kay, J, Gadolinium-Induced Fibrosis. Annual Review of Medicine, 2016. 67:273-91: p. 284.

57. At least by 2009 Defendants could and should have known of the consequences of gadolinium retention in people with normal renal function because they were put on notice of the risks of gadolinium retention in 2007 when the FDA ordered Defendants to change their label. The evidence of NSF being caused by GBCAs was overwhelming and there was significant evidence of retention in people with normal renal function. The adverse events, and studies as set forth herein further demonstrated the health effects in people with ordinary renal function. Defendants confirmed their knowledge and understanding that the adverse effects of gadolinium are on a "continuum" with NSF being the most severe manifestation in testimony to the FDA in 2017. *See* ¶ 114. The evidence this testimony was based upon was largely available for years prior to that testimony.

58. Defendants failed to warn Plaintiff and her healthcare providers about the serious health risks associated with linear gadolinium-based contrast agents, and failed to disclose the fact that there were safer alternatives (e.g., macrocyclic agents instead of linear agents).

59. It was reasonably foreseeable that that Defendants' drugs would cause gadolinium retention, fibrosis, and related injuries.

60. Defendants engaged in a deliberate and conscious effort to disregard the obvious logical conclusion that because gadolinium toxicity is not caused by impaired renal function, it is thus is a danger to people without diagnosed renal insufficiency. These Defendants intentionally and consciously chose not to engage in immediate and thorough research on risks of gadolinium retention and toxicity in patients with normal renal function because they did not want to undermine their products, thereby reducing profits.

61. "Newly acquired information'" is not limited to new data, but also encompasses

"new analyses of previously submitted data." Defendants could and should have re-analyzed the safety information they had on their GBCAs. Based on this new health and safety information, at any time post-approval, Defendants should have sought a label change, including doing it without first obtaining FDA approval under what is called a "Changes Being Effected (CBE)" label change.

62. By the time Plaintiff received her linear GBCA injections, Defendants knew gadolinium from their GBCAs was found in people with impaired renal function, but their renal impairment was not the cause of their retention. Defendants knew that Japanese researchers found gadolinium in the brains of people with normal renal function. Defendants had already been in discussions with European regulators at the European Medicines Agency and been ordered to conduct further research on the retention and effects of gadolinium in people with normal renal function. Even though Defendants knew of these serious health reports, they nonetheless failed to timely and adequately warn its customers, including Plaintiff and her healthcare providers, about the serious health risks of gadolinium retention.

63. As a direct and proximate result of receiving injections of linear gadolinium-based contrast agents manufactured, distributed, marketed, and/or sold by Defendants, Plaintiff has suffered severe physical injury and pain and suffering, including, but not limited to, gadolinium retention resulting in fibrosis in her organs, skin, and bones, retained gadolinium in her brain, and related injuries.

64. Defendants have repeatedly and consistently failed to advise consumers and their healthcare providers of the causal relationship between linear gadolinium-based contrast agents and gadolinium retention resulting in fibrosis in the organs, skin, and bones, retained gadolinium in the brain, and related injuries. Defendants knew or should have known of the risks posed by linear gadolinium-based contrast agents to individuals with normal or near-normal kidney function.

65. Had Plaintiff and/or her healthcare providers been warned about the risks associated with linear gadolinium-based contrast agents, she would not have been administered

linear gadolinium-based contrast agents and would not have been afflicted with gadolinium retention resulting in fibrosis in her organs, skin, and bones, retained gadolinium in her brain, and related injuries.

66. As a direct and proximate result of being administered linear gadolinium-based contrast agents, Plaintiff suffered and continues to suffer significant mental anguish and emotional distress and will continue to suffer significant mental anguish and emotional distress in the future.

67. As a direct and proximate result of being administered linear gadolinium-based contrast agents, Plaintiff has also incurred medical expenses and other economic damages and will continue to incur such expenses in the future.

68. The nature of Plaintiff's injuries and damages, and their relationship to linear gadolinium-based contrast agents, were not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiff, until a time less than three years before the filing of her complaint. Prior to filing her complaint, Ms. Sabol took a urine test on April 8, 2016 that conclusively demonstrated the continued presence of toxic levels of gadolinium in her body.

69. While Plaintiff was not aware of the history of evidence regarding the dangers of GBCAs, Defendants knew or should have known of these risks as early as 1984.

70. Since as early as 1984, medical and scientific literature have reported on the deposition of toxic gadolinium in animal tissue.

71. In 1988, Bayer's Magnevist, a linear GBCA, was the first GBCA to gain FDA approval for marketing and sale in the United States, and by that time, Bayer was aware of the evidence of gadolinium deposition in biological systems.

72. September 1989 may have marked the very first report of the retention of toxic gadolinium in a human, when Tien et al. reported that intracerebral masses "remained enhanced on MRI images obtained 8 days after injection of gadolinium DTPA dimeglumine (Magnevist)." *See* Tien, R.D., et al., *Cerebral Erdheim-Chester Disease: persistent enhancement with Gd-*

DTPA on MR images, Radiology, 1989; Vol. 172, No. 3, p. 791-92. Subsequent chemical analysis revealed that a high concentration of gadolinium remained in the tissue.

73. In 1993, shortly after FDA's approval of another linear GBCA, General Electric's Omniscan, preclinical safety assessment and pharmacokinetic data were published describing its pharmacokinetics in rats, rabbits, and cynomolgus monkeys. These studies showed that quantifiable concentrations of gadolinium were persistent in both the renal cortex and areas around bone cartilage.

74. Throughout the 1990s, evidence showing retention of gadolinium in human patients with renal (kidney) insufficiency was mounting, and by 2004, evidence clearly began to show deposition of gadolinium in human patients *without* compromised renal function.

75. In 2000, a new scleroderma-like cutaneous disorder was described by Cowper that first presented in 15 dialysis patients and was called nephrogenic fibrosing dermopathy (NFD) (Cowper et al. 2000). Gross diagnostic symptoms included persistent skin induration (increase in tissue fibrous elements marked by loss of elasticity and pliability that are commonly associated with inflammation; hardened skin masses or skin formations), dermal thickening, and hyperpigmentation – all presenting mainly in the extremities and trunk with facial sparing. NSF was initially believed to be confined to the skin and was named nephrogenic fibrosing dermopathy (NFD). In some patients, however, there is clinical involvement of other tissues (lung, skeletal muscle, heart diaphragm, esophagus, etc.) and this disease is now referred to as NSF. NSF evolves abruptly (days to weeks), with conditions that include skin discoloration and thickening, joint contracture, muscle weakness, and generalized pain (Cowper et al. 2000).

76. NSF is a disease that can result in disease and death among those affected. High et al. (2007) observed that the cause of NSF was a mystery in the medical community for almost a decade.

77. By 2004, gadolinium had been shown to be deposited in the resected femoral

heads (bones) of people who had undergone gadolinium MRI studies.[20] Since then, studies have continued to indicate that gadolinium from GBCAs remains within people's bodies long after their suggested half-lives.

78. In 2006, Grobner first proposed that GBCAs triggered the development of NSF in dialysis patients with underlying metabolic acidosis (Grobner 2006). Prior to this report, only severe or end-stage kidney disease had been associated with NSF.

79. In 2007, High et al. reported their results of examining skin and soft tissues from NSF patients with documented NSF who were exposed to GBCAs, as well as control patients who had no GBCA exposure. The investigators found detectable gadolinium in 4 of 13 tissue specimens from 7 patients with documented NSF who were exposed to GBCAs.

80. As direct consequence of the skyrocketing use of GBCAs in MRI in the 1980s and 1990s, by the early 2000s, the medical and scientific community began to take note of this never-before-seen disease that was arising in patients with compromised renal function who had been exposed to GBCAs.

81. The disease was characterized by fibrosis of the skin and/or internal organs. Initially the condition was called "nephrogenic fibrosing dermopathy," but eventually came to be known as it is today: nephrogenic systemic fibrosis, or "NSF."

82. NSF was uncovered and understood only by the attentive clinical observation and work of dermatologists, nephrologists, and other scientists, who connected the administration of *linear* GBCAs to this rapidly progressive, debilitating and often fatal condition.

83. There were over 500 cases of NSF reported, and it was estimated there were well over a thousand non-reported cases.

84. Eventually, the emergence of NSF prompted the FDA to require GBCA manufacturers, including all Defendants, to strengthen the class product labeling for GBCAs to

[20] Gibby WA, Gibby KA, Gibby WA. Comparison of Gd DTPA-BMA (Omniscan) versus Gd HP-DO3 (ProHance) retention in human bone tissue by inductively coupled plasma atomic emission spectroscopy. Invest Radiol., 2004; 39:138-142.

include a "black box" warning, which first went into the labeling in 2007:

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)

See full prescribing information for complete boxed warning.

Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities.

• Do not administer Magnevist to patients with:

o chronic, severe kidney disease (GFR < 30 mL/min/1.73m2), or

o acute kidney injury.

• Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (for example, age > 60 years, hypertension, or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.

85. Because of the black box warning, and the medical community's awareness of the clear causal connection between GBCAs and NSF in renally impaired patients, the incidence of NSF has all but disappeared, as healthcare practitioners have universally changed MRI prescription habits.

86. Once the black box warning was added to GBCAs in 2007 for patients with abnormal kidney function, adverse event reports (AERs) to the FDA for NSF declined precipitously, but AERs for similar symptoms in people with normal renal function were and continue to be reported in significant numbers. The continuing AERs were a clear signal to the manufacturers that retained gadolinium was causing symptoms in people with normal renal function.

87. As manufacturers and sellers of Magnevist, MultiHance, and Omniscan, the onus is/was on Defendants to ensure the safety of their products. After NSF was discovered in patients with clinically diagnosed renal impairment, Defendants could have and should have researched GBCA safety and the possibility/effects of retention in patients not clinically

diagnosed with renal impairment.

88. In 2007 (and today), there was no evidence that impaired renal function was the *cause* of NSF. Therefore, because renal impairment is not the *cause* of NSF, Defendants could have and should have used this newly acquired information and evidence to sound the alarm that non-renally impaired recipients of their linear GBCAs were at risk for gadolinium retention and toxicity.

89. A rigorous review of the literature by Broome (2008) subsequently showed a strong association with NSF and GBCA exposure. When NSF was first recognized as being associated with GBCAs used in MRI imaging, several registries and watch programs were established to record and follow case reports and case series. These included U.S. FDA's MedWatch Program, the U.K. Commission on Human Medicines, and European Pharmacovigilance Working Group. In 2008, Broome summarized all NSF case reports and case series in the peer-reviewed literature that were biopsy-proven NSF cases (in the absence of biopsy, NSF can resemble other cutaneous disorders), and determined that the vast majority were associated with three GBCAs: 157 cases with Omniscan (gadodiamide, a linear GBCA); 8 with Magnevist (gadopentetate, a linear GBCA); and 3 with Optimark (gadoversetamide, a linear GBCA); 18 unspecified GBCAs; and 4 confounded cases who had been given more than one GBCA. Only five NSF cases were unassociated with GBCA exposure.

90. Laboratory (in vitro) studies assessing the stability of each gadolinium-based contrast agent in human blood were performed and demonstrated that, over time, greater percentages of gadolinium were released from linear agents as compared to the macrocyclic agents.[21]

91. Some patients sent letters to the FDA as early as 2012, warning about the occurrence of gadolinium toxicity in those with normal renal function following injections of

[21] Tweedle MF, Eaton SM, Eckelman WC, et al. *Comparative chemical structure and pharmacokinetics of MRI contrast agents*. Invest. Radiol. 1988; 23 (suppl 1): S236-S239; see also Frenzel T, Lengsfeld P, Schimer H, et al. *Stability of gadolinium-based magnetic resonance imaging contrast agents in serum at 37 degrees* C. Invest. Radiol. 2008; 43:817-828.

gadolinium-based contrast agents.

92. In 2013, while examining non-contrast enhanced MRI images, Japanese researchers, Kanda, et al., found evidence of retained gadolinium in the brains of patients with normal renal function that had previously received one or more injections of gadolinium-based contrast agents up to several years prior. They found that the brain had hyperintense signals in critical areas of the brain.[22]

93. In May 2013, a study was initiated to further investigate the safety of six different commercially used gadolinium-containing contrast agents. The study was requested by the European Medicines Agency to further investigate whether Gadolinium in human bone and skin are retained for a long time after administration of gadolinium-containing contrast agents. The study was developed to evaluate gadolinium retention in patients with renal function ranging from stable to severely impaired renal function.

94. These findings were confirmed by scientists at the Mayo Clinic in 2014 when autopsy studies were performed on 13 deceased individuals, all of whom had normal or near normal renal function and who had received six or more injections of gadolinium-based contrast agents in the years prior. Up to 56 mcg of gadolinium per gram of desecrated tissue were found within the brains of these patients.[23]

95. When comparing the incidents following exposure to macrocyclic and linear GBCAs, the incidence was much higher with linear GBCAs (High et al. 2007, Saussereau et al. 2007, Layne et al. 2018, Ramalho et al. 2017, Murata et al. 2016, Robert et al. 2015, Robert et al. 2018b).

96. The association between NSF and kidney disease is attributed to the delay in elimination caused by slow glomerular filtration rates and other impaired renal function such

[22] Kanda T, Ishii K, Kawaguchi H, et al. High signal intensity in the dentate nucleus and globus pallidus on unenhanced T1-weighted MR images: relationship with increasing cumulative dose of a gadolinium-based contrast material. *Radiology*. 2014; 270: 834-841.

[23] McDonald RJ, McDonald JS, Kallmes DF, et al. Intracranial gadolinium deposition after contrast-enhanced MR imaging. *Radiology*. 2015; 275:772-782.

those caused by acute kidney disease (Rogosnitzky and Branch 2016). NSF is classified as a multi-organ fibrosing disorder that occurs in both genders and all ethnic groups and has been observed in patients of all ages although the majority of cases occur in adults between 30 and 60 years (Cowper et al. 2000, Kanda et al. 2016, Idée et al. 2009).

97. It is undisputed that GBCAs cause NSF, and renal insufficiency is simply a catalyst (Leyba and Wagner 2018). More than 98% of NSF cases occurred in patients who had undergone studies with the linear GBCAs Omniscan, Optimark, or Magnevist. (Lenkinski 2017).

98. NSF is debilitating physically and cognitively, and can also be lethal (Broome 2008). Early clinical manifestations of NSF include pain, swelling, skin erythema, pruritus (severe itching of the skin), transient alopecia (hair loss), gastrointestinal symptoms of nausea, vomiting, diarrhea and abdominal pain, as well as dizziness, mental confusion or "fog" (Broome 2008, Parillo et al. 2018).

99. These reports and studies revealing gadolinium retention and physical consequences arising therefrom revealed risks of a different type and greater severity or frequency than previously included in submissions to the FDA. *See Gibbons v. BMS*, 919 F.3d 669, 708 (2d Cir. 2019). They revealed that the kidney is not the cause of NSF, but rather a catalyst. They revealed that people with normal renal function suffer from retained gadolinium. They revealed that gadolinium retention causes a variety of physical injuries and impairments. These constitute risks of a different type with greater severity and greater frequency because the at-risk population is *everyone*, not merely those with impaired renal function .

100. Macrocyclic GBCAs such as gadoteridol (ProHance), gadobutrol (Gadovist) and gadoterate meglumine (Dotarem) pose a lower risk of transmetallation compared to linear GBCAs because of stronger binding and chemical stability under physiologic conditions (Idée et al. 2006). Data collected over the past decade support this ranking of potential toxicity among GBCAs; further, dose levels, frequency of MRI administration and pre-existing risk factors affect health risks posed by individual GBCAs (Lohrke et al. 2016).

101. At all times relevant to this Complaint, a safer and equally efficacious macrocyclic alternative was available and produced by each of the Defendant manufacturers. Because of their structure, macrocyclic GBCAs are more stable and less prone to de-chelation—and hence deposition—in the body. Indeed, laboratory (in vitro) studies assessing the stability of various GBCAs in human blood have demonstrated that, over time, greater percentages of gadolinium are released from linear agents as compared to the macrocyclic agents. Macrocyclic GBCAs are and were not retained to the same extent in the human body and this was known at all relevant times by each Defendant. The Defendants nevertheless deliberately chose to continue to market and sell the more dangerous and higher retention linear products.

102. It is now settled in the medical community that GBCAs are a cause of NSF. Authoritative and reliable medical literature has reported that the relative risk for development of the disease in renally impaired patients exposed to GBCAs might be as high 41 (a 4,000% increased risk over baseline) compared to baseline. *See* Wagner, B., et al. *Pathophysiology of gadolinium-associated systemic fibrosis*, Am. J. Physiol. Renal Physiol., 311(1): p. F1-F11 (2016).

103. To be sure, the kidneys play a central role in the body's clearance of GBCAs, but the name "nephrogenic" systemic fibrosis is misleading, as there is in fact no evidence that this systemic fibrotic condition is in any way *caused* by the kidneys. Instead, the kidneys are simply a catalyst, insofar as impaired renal function results in the body's prolonged exposure to a GBCA dose from an imaging event.

104. In July of 2015, in response to the Mayo Clinic study's findings, the FDA issued a new public safety alert stating that the FDA is evaluating the risk of brain deposits from repeated use of gadolinium-based contrast agents used in MRIs.

105. Despite this well-documented evidence of gadolinium retention, Defendants have continuously failed to warn consumers and their healthcare providers on the label of their products, or anywhere that a patient or physician could be informed.

106. Gadolinium toxicity is an underreported and underdiagnosed condition. Over the

past several years (since the link between gadolinium-based contrast agents and NSF was acknowledged) patients with normal renal function have been forming advocacy groups and coming forward to create awareness for their condition. Symptomatic patients often have documentation of high levels of gadolinium in their blood and urine long after their exposure to gadolinium-based contrast agents. Some patients also have tissue biopsies of various parts of their body that show additional evidence of retained gadolinium years after their exposure.

107. In Europe, GBCAs are regulated by the European Medicines Agency (EMA). Following reports of gadolinium accumulation in animals and in humans in organs such as liver, kidney, muscle, skin and bone, and deposition in brain tissue of patients, on March 3, 2016, the European Commission (EC) directed EMA to review GBCAs as part of an Article 31 referral (EC 2016). Article 31 referrals are triggered over concerns relating to the "quality, safety, or efficacy of a medicine or a class of medicines."

108. On July 20, 2017, following a comprehensive review of GBCAs, EMA's Pharmacovigilance Risk Assessment Committee (PRAC) concluded that available evidence established that gadolinium deposition occurs in brain tissues following use of GBCAs, and based on this deposition and known toxicity of gadolinium and identified risks of linear GBCAs, recommended suspensions or restrictions on the use of four linear GBCA agents for intravenous uses, as shown in Table 2 (EMA 2017a,b).

109. The EC accepted EMA's recommendations to restrict and/or suspend these GBCAs, and on November 23, 2017, the EC issued a legally binding decision applicable in all EU Member States (EMA 2017c).

110. In addition to the European Medicines Agency, several foreign countries banned or restricted the use of several linear GBCAs, or added additional warnings before the United States took any action. These include the United Kingdom, Singapore, Canada, and Japan.

111. In 2017, the U.S. FDA completed an examination of the effects of gadolinium accumulation in individuals with normal kidney function and confirmed exposure to GBCAs. Specifically, FDA evaluated adverse events reported in 139 patients (41 cases in FAERS and 98

cases in the medical literature reported since 1988) in conjunction with gadolinium retention after GBCA exposure (including exposure to linear GBCAs, macrocyclic GBCAs, and both). All cases had confirmed gadolinium exposure. Of the 41 FAERS cases, 28/41 subjects reported exposure to linear GBCAs. Of the 98 cases reported in the medical literature, 56 cases were associated with linear GBCAs, while 4 cases were associated with macrocyclic GBCAs, and 38 cases were associated with unknown GBCA (36 cases) or 2 (mixed GBCAs) exposure.

112. U.S. FDA's analysis of cases identified consistent clustering around cutaneous, musculoskeletal, cognitive/neurological, and pain syndrome clinical categories following exposure to GBCAs.

113. The U.S. FDA's 2017 analyses provides an initial snapshot of adverse events associated with exposure to linear GBCAs, but likely underestimates the morbidity and mortality caused by exposure to linear GBCAs. The number of serious cases from any of the six linear GBCAs reported in the FAERS database (1988-present) totals 10,841 AERs, and more than 623 serious AERs reported in 2017 and 2018.

114. In September 2017, the FDA's Medical Imaging and Drug Advisory Committee voted 13 to 1 in favor of adding a warning on labels that gadolinium can be retained in some organs, including the brain, even in patients with healthy kidneys. Dr. Pierre Desche spoke on behalf of Guerbet regarding their GBCA at that meeting. He stated, "[B]rain hyperintensities and NSF are, in fact, part of the same continuum from gadolinium retention to gadolinium toxicity, and renal dysfunction acts as a catalyst." At the same meeting, Dr. Gene Williams, an FDA clinical pharmacologist said "…[i]f you had information on patients with varying degrees of renal impairment and you could tease out the effect of the renal impairment itself, you might expect it to be a continuum." Thus, Defendants knew that NSF was not caused by impaired renal function but rather by their toxic heavy metal gadolinium and they knew that some people were having problems on a continuum.

115. In December 2017, the FDA required a new class warning and other safety measures for all gadolinium-based contrast agents for MRIs concerning gadolinium remaining

in patients' bodies, including the brain, for months to years after receiving these drugs. The FDA required manufacturers to issue a patient medication guide, providing educational information that every patient must be asked to read before receiving a GBCA. The FDA also required manufacturers of GBCAs to conduct human and animal studies to further assess their safety.

116. In May, 2018, the GBCA manufacturers finally issued a joint warning to patients with normal kidney function. This new "Important Drug Warning" issued by Bayer, GE, Bracco, and Guerbet included the following:

a. "Subject: Gadolinium from GBCAs may remain in the body for months to years after injection;"
b. A new class warning, patient counseling, and a medication guide;
c. Warning that gadolinium is retained for months to years in several organs;
d. Warning that the highest concentrations of retained gadolinium are found in bone, followed by organs (brain, skin, kidney, liver, and spleen);
e. Warning that the duration of gadolinium retention is longest in bone and varies by organ;
f. Warning that linear GBCAs cause more retention than macrocyclic GBCAs;
g. Warning about reports of pathological skin changes in patients with normal renal function;
h. Warning that adverse events involving multiple organ systems have been reported in patients with normal kidney function;
i. Warning that certain patients are at higher risk:
    i. patients with multiple lifetime doses;
    ii. pregnant patients;
    iii. pediatric patients;
    iv. patients with inflammatory process;
j. Instructions for health care providers to advise patients that:
    i. Gadolinium is retained for months or years in brain, bone, skin, and

other organs in patients with normal renal function;

ii. Retention is greater following administration of linear GBCAs than following administration of macrocyclic GBCAs.

117. The current label, which includes the new 2018 warnings, has had the effect of radically reducing sales of linear GBCA products in the United States. Doctors and patients recognize, based upon the current warning, that the linear agents cause the toxic heavy metal gadolinium to be retained at a much higher rate than the equally-efficacious macrocyclic agents, and as a result, are stopping usage of the linear products.

118. Defendants have had all the information required to request a CBE label change containing the information set forth in the current label for many years. By 2007, when the FDA added the black box warning for NSF, it was already known by the Defendants that gadolinium was released from the chelate and could cause fibrosis throughout the human body. Rather than warning all patients about gadolinium release and retention, Defendants chose to limit the warning to a small subset of patients who had abnormal renal function.

119. Had the May 2018 warning been given prior to any of Plaintiff Marcia Sabol's linear GBCA administrations, her doctors would not have prescribed a linear agent and/or Marcia Sabol would have declined a linear agent and instead requested a macrocyclic agent be prescribed due to its lower retention characteristics and accordingly increased safety.

120. In 2018, the FDA noted that "… after additional review and consultation with the Medical Imaging Drugs Advisory Committee, we are requiring several actions to alert health care professionals and patients about gadolinium retention after and MRI using a GBCA, and actions that can help minimize problems." [24] FDA stated that doctors should "[m]inimize repeated GBCA imaging studies when possible, particularly closely spaced MRI studies."[25] Therefore, it is incorrect to believe that that the FDA ruled out linear GBCAs as a cause for the adverse events reported by patients.

121. FDA does not warn about retention of benign substances. Rather, a warning is

[24] Exhibit B to Complaint at p. 1.
[25] *Id.* at 1-2.

required when FDA considers a risk significant: "The WARNINGS AND PRECAUTIONS section is intended to identify and describe a discrete set of adverse reactions and other potential safety hazards that are *serious* or are *otherwise clinically significant* because they have implications for prescribing decisions or for patient management."[26] FDA guidance about when to include an adverse event in the Warnings section mandates: "To include an adverse event in the section, there should be reasonable evidence of a causal association between the drug and the adverse event, but acausal relationship need not have been definitively established." *Id.* Here, the strengthened warning specifically states that "[a]dverse events involving multiple organ systems have been reported in patients with normal kidney function…" Those adverse events plainly meet the FDA standard of "reasonable evidence of a causal association" or that statement would not have been included in the approved warning.

122. Prior to May, 2018, Defendants failed to warn Plaintiff, her health care providers, and other patients and doctors throughout the United States about the specific concerns and warnings listed in the preceding paragraphs.

123. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiff the nature of Plaintiff's injuries and the connection between her injuries and the Defendants' tortious conduct.

FIRST CAUSE OF ACTION
(Against All Defendants)
STRICT PRODUCT LIABILITY: FAILURE TO WARN

124. Plaintiff incorporates by reference and realleges each paragraph set forth above.

125. Defendants' linear gadolinium-based contrast agents were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing.

126. Magnevist, MultiHance, and Omniscan were defective at the time of their manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying Magnevist, MultiHance,

[26] Exhibit C to Complaint– FDA Industry Guidance at p. 3 (emphasis in original)

and Omniscan failed to warn of the dangerous risks posed by Magnevist, MultiHance, and Omniscan, including the risk of gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain.

127. At all times alleged herein, Magnevist, MultiHance, and Omniscan were defective and Defendants knew that Magnevist, MultiHance, and Omniscan were to be used by consumers without inspection for defects. Moreover, Plaintiff, her prescribing physicians, and her health care providers neither knew nor had reason to know at the time of Plaintiff's use of Magnevist, MultiHance, and Omniscan of the aforementioned defects. Ordinary consumers would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

128. At all times alleged herein, Magnevist, MultiHance, and Omniscan were prescribed to and used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.

129. The designs of Magnevist, MultiHance, and Omniscan were defective in that the risks associated with using Magnevist, MultiHance, and Omniscan outweighed any benefits of the design. Any benefits associated with the use of Magnevist, MultiHance, and Omniscan were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results.

130. The defect in design existed when the product left Defendants' possession.

131. At the time Magnevist, MultiHance, and Omniscan left the control of Defendants, Defendants knew or should have known of the risks associated with use of Magnevist, MultiHance, and Omniscan.

132. Defendants are all manufacturers and nonmanufacturers in the subject products' chain of distribution, and defects in said products caused Plaintiff's personal injuries. Said defects in Defendants' products were a substantial factor in bringing about the injuries suffered by Plaintiff, who was using said products in the manner normally intended at the time of the

occurrence. Plaintiff could not, by the exercise of reasonable care, have discovered the defect or perceived of its danger, nor could he, by the exercise of reasonable care, have avoided the injury.

133. Defendants are liable for their absence and inadequacy of a warning of latent dangers resulting from the foreseeable uses of Magnevist, MultiHance, and Omniscan of which they knew or should have known, and for breaching their post-sale duty to warn.

134. Defendants' linear gadolinium-based contrast agents were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing.

135. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, yet Defendants failed to adequately warn consumers and their healthcare providers of such risks.

136. Magnevist and its labeling were approved by the FDA on June 2, 1988. The other GBCAs were approved thereafter.

137. Between June 2, 1988 and May 2007 (the date of Ms. Sabol's first Magnevist injection), new evidence emerged regarding the health effects of GBCAs and gadolinium's tendency to cause fibrosis when it is released from its chelate. New evidence had also emerged regarding the health effects of Omniscan and MultiHance's tendencies to cause fibrosis when they're released from their chelates.

138. The fibrotic injuries and symptoms experienced by Ms. Sabol and other patients with normal renal function are on the same continuum as NSF, and this was learned by Bayer between 1988 and 2007. This evidence was also known to Bracco, GE Healthcare Inc., and General Electric Company by the time Ms. Sabol was given their products.

139. This newly acquired evidence was clear evidence of the detrimental health effects of Magnevist, Multihance, and Omniscan, which should have prompted Defendants to change their labels.

140. Defendants did not make any efforts to change their labeling to warn consumers like Ms. Sabol of the newly acquired evidence. Therefore, Defendants cannot establish clear

evidence that shows the Court that they fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer Defendants that the FDA would not approve a change to the drug's label to include that warning.

141. This newly acquired evidence showed a causal association with a clinically significant adverse reaction.

142. Between June 2, 1988 and May 2007, Defendants had the option to correct the Magnevist, MultiHance, and Omniscan labels using the CBE (Changes Being Effected) regulations, but failed to do so.

143. The newly discovered evidence of clinically significant symptoms and injuries would have allowed Defendants to use the CBE regulations in order to make a labeling amendment.

144. In light of this newly discovered evidence, and the labeling options available to Defendants, the Magnevist, MultiHance, and Omniscan labels were deficient at the time that Ms. Sabol was administered Magnevist, MultiHance, and Omniscan.

145. In addition, in 2007, new warnings were added to the Magnevist, MultiHance, and Omniscan labels. At that time, Defendants made a conscious decision to only warn a limited patient population (those with abnormal renal function) when Defendants knew that patients with normal renal function, like Ms. Sabol, were also at risk of injury if administered Magnevist, MultiHance, or Omniscan.

146. Once Defendants amended their labeling to warn of the risk of NSF, GBCAs were no longer given to people with impaired renal function. Yet, adverse event reports continued to be made—by people with ordinary renal function—putting Defendants on notice of the problem which has been confirmed by the retention studies. Because Defendants knew that kidneys were not the cause of NSF, but merely a catalyst, Defendants were aware that people with normal renal function were also at risk of physical injury and should have and could have immediately amended their labels using the CBE provision to implement such changes.

147. Because Ms. Sabol’s injuries are the result of fibrosis caused by gadolinium

retention, her injuries were foreseeable to Defendants, and could have been prevented by Defendants.

148. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Magnevist, MultiHance, and Omniscan, and through that conduct have knowingly and intentionally placed Magnevist, MultiHance, and Omniscan into the stream of commerce with full knowledge that they reach consumers such as Plaintiff who received it.

149. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Magnevist, MultiHance, and Omniscan to Plaintiff and to her prescribing physicians. Additionally, Defendants expected the Magnevist, MultiHance, and Omniscan that they were selling, distributing, supplying, manufacturing, and/or promoting to reach – and Magnevist, MultiHance, and Omniscan did in fact reach – prescribing physicians and consumers, including Plaintiff and her prescribing physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

150. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and ingested by Plaintiff. The defective condition of Magnevist, MultiHance, and Omniscan was due in part to the fact that they were not accompanied by proper warnings regarding the possible side effect of developing long-term and irreversible gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposits in the neuronal nuclei of the brain, as a result of its use.

151. This defect caused serious injury to Plaintiff, who used Magnevist, MultiHance, and Omniscan in their intended and foreseeable manner.

152. At all times herein mentioned, Defendants had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that the product did not

cause users to suffer from unreasonable and dangerous side effects.

153. Defendants so negligently and recklessly labeled, distributed, and promoted the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.

154. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with Magnevist, MultiHance, and Omniscan.

155. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that Magnevist, MultiHance, and Omniscan cause serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing irreversible gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain, from Magnevist, MultiHance, and Omniscan use, even though this side effect was known or reasonably scientifically knowable at the time of distribution. Defendants willfully and deliberately failed to avoid the consequences associated with their failure to warn, and in doing so, Defendants acted with a conscious disregard for the safety of Plaintiff.

156. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

157. Defendants, as the manufacturers and/or distributors of the subject product, are held to the level of knowledge of an expert in the field.

158. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

159. Had Defendants properly disclosed the risks associated with Magnevist, MultiHance, and Omniscan, Plaintiff would have avoided the risk of gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain, by not using Magnevist, MultiHance, and Omniscan.

160. As a direct and proximate result of the carelessness, negligence, recklessness, and gross negligence of Defendants alleged herein, and in such other ways to be later shown, the subject product caused Plaintiff to sustain injuries as herein alleged.

161. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such, Plaintiff is entitled to exemplary or punitive damages.

162. WHEREFORE, Plaintiff demands judgment against Defendants in a sum well in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

SECOND CAUSE OF ACTION
(Against All Defendants)
NEGLIGENCE

163. Plaintiff incorporates by reference and realleges each paragraph set forth above.

164. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Magnevist, MultiHance, and Omniscan.

165. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

166. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not limited to, one or more of the following particulars:

a) In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of Magnevist, MultiHance, and Omniscan;

b) In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of Magnevist, MultiHance, and Omniscan's dangerous and defective characteristics;

c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for the subject product;

d) In promoting the subject product in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause irreversible gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain;

e) In representing that the subject product was safe for its intended use when, in fact, the product was unsafe for its intended use;

f) In failing to perform appropriate pre-market testing of the subject product;

g) In failing to perform appropriate post-market surveillance of the subject product;

h) In failing to adequately and properly test Magnevist, MultiHance, and Omniscan before and after placing them on the market;

i) In failing to conduct sufficient testing on Magnevist, MultiHance, and Omniscan which, if properly performed, would have shown that Magnevist, MultiHance, and Omniscan had the serious side effect of causing gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the

neuronal nuclei of the brain;

j) In failing to adequately warn Plaintiff and her healthcare providers that the use of Magnevist, MultiHance, and Omniscan carried a risk of developing irreversible gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain;

k) In failing to provide adequate post-marketing warnings or instructions after Defendant knew or should have known of the significant risk of gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain, associated with the use of Magnevist, MultiHance, and Omniscan; and

l) In failing to adequately and timely inform Plaintiff and the healthcare industry of the risk of serious personal injury, namely irreversible gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain, from Magnevist, MultiHance, and Omniscan use as described herein.

167. Defendants knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

168. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin),

the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

169. WHEREFORE, Plaintiff demands judgment against Defendants in a sum well in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

(a) For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses according to proof;

(c) For pre-judgment and post-judgment interest as provided by law;

(d) For compensatory damages in excess of the jurisdictional minimum of this Court;

(e) For consequential damages in excess of the jurisdictional minimum of this Court;

(f) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;

(g) For attorneys' fees, expenses, and costs of this action; and

(h) For such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

In addition to the above, Plaintiff hereby demands a trial by jury for all causes of action and issues that can be tried by a jury.

Dated this 15th day of July 2019

By: */s/ Todd A. Walburg*

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CERTIFICATE OF SERVICE

I, Todd Walburg, hereby certify that on July 15, 2019, a copy of this First Amended Complaint was filed electronically. Notice of this filing will be sent to all parties by operation of this Court's CM/ECF.

/s/ Todd Walburg
Todd Walburg